REMARKS

A petition for a two month extension of time, and authorization to charge the fee is included herewith.

Applicants not with appreciation Examiner's withdrawal of the restriction requirement to claims 55-72. Examiner further stated that claims 25-54 were withdrawn. Accordingly, Applicants believe the pending claims are 1, 4-11, 14-17, 19, 21-24 and 55-72. Confirmation is respectfully requested.

Claims 55, 63, 64, 68, 71 have been amended to recite that silver is present in an amount up to about 200 ppm. Support for this amendment may be found at Tables 3 and 4 on pages 48-48 and Figures 1 and 2. Claim 62 has been canceled without prejudice to present it in a later application. Claims 64-67 and 72 have been amended to recite more clearly that the recited lenses have sufficient movement on the recited percentages of patients wearing said lens. Support for this amendment may be found at page 32, lines 6-8. Entry of the amendments is requested.

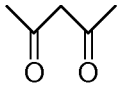
Examiner has rejected claims 55-61 and 63-72 as unpatentable over JP 05-269181 or EP1050314, each in view of Vanderlaan et al. (US 5,998,498), Laskey (US 3,929,741) JP 55-38855, Malecki et al. Tilley, Bennet and Young.

Applicants first address the rejections of claims 55-61 and 63-72 based upon JP 05-269181 in view of Vanderlaan et al., Laskey, JP 55-38855, Malecki et al., Tilley, Bennet and Young.

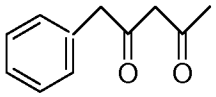
JP 05-269181 ("JP `181) discloses making resin moldings antimicrobial by incorporating certain antimicrobial complexes into or onto the resins.

> "antimicrobial metal acetylacetonate complexes such as acetylacetonatometal complexes or benzoylacetonate complex salts such as benzoylacetonatometal complexes are soluble in many polymerizable monomers forming transparent plastics suitable for contact lenses, and can be strongly incorporated in polymer compositions. As a result of further study, we have also discovered that by adding a radical-polymerizable unsaturated double-bond-containing function group to the benzene ring of the benzoylacetonatometal complex, the antimicrobial material can be directly incorporated into the polymer chain." JP `181, page 7, paragraphs 11 and 12.

Acetylacetonate has the following structure:



Benzoylacetonate has the following structure:



Many other antimicrobial agents are suggested by JP `181 (chitosans, paragraphs 13-14; chlorhexidine, paragraphs 15-17, ethacridine, paragraphs 18-20 and quaternary ammonium salts, paragraphs 21-23). However, none of these other antimicrobial agents have the structure recited in Formula I or claim 1. Neither does JP `181 suggest their use with silver. To the extent that JP `181 suggests alternatives for acetonate metal complexes, it suggests organic, non-metal containing antimicrobials.

Vanderlaan discloses soft contact lenses formed from silicone hydrogels comprising specific monoalkyl terminated siloxane monomers (Column 2, lines 24-43). The use of any antimicrobial agents or binding monomers, let alone those of the present invention is not disclosed or suggested.

Laskey discloses polymer compositions comprising a hydrophilic polymer obtained by polymerization of an acrylamido alkyl sulfonic acid monomer which have the ability to ingurgitate water "in extremely high quantities, even up to 400 times the weight of the polymer." See column 1, lines 31 through 36. "[C]omonomers can be used to alter the physical properties of the polymer and the amount of aqueous liquid which can be ingurgitated by the polymer. The amount of such co-monomer may be up to 50% of the total, though generally smaller amounts may be used." (Column 4, lines 29-33). Laskey is also silent with respect to the incorporation of antimicrobial agents of any kind.

There is nothing in Laskey to suggest that (a) the acrylamido alkyl sulphonic acid monomers could be used for any purpose, other than the ingurgitation of water; (b) silver should be incorporated into the polymers formed from the monomers disclosed therein, or (c) the resulting articles would be antimicrobial.

Malecki et al. and Tilley disclose methods of determining stability constants of silver with various ligands. Ligands within formula 1 as recited in claims 55 and 63 are not disclosed or suggested. Specifically, neither Malecki et al. nor Tilley disclose ligands having a terminal vinyl group. Malecki et al. and Tilley also do not suggest incorporating the ligands disclosed therein into any polymeric substrate, let alone a contact lens.

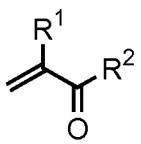
Bennett discussed lens performance factors for "successful wear of RGP lenses". S5. Antimicrobial contact lenses of any kind and antimicrobial contact lenses comprising the monomers of formula I are not disclosed or suggested. Bennett is absolutely silent as to the factors which effect lens movement in any lens, let alone a lens comprising a monomer of Formula I and at least one antimicrobial metal.

Young discloses methods for determining contact lens movement. Antimicrobial contact lenses of any kind and antimicrobial contact lenses comprising the monomers of formula I are not disclosed or suggested.

JP 55-38855 ("JP `855) discloses "antimicrobial materials of which the principal component is a polymeric substance that contains sulfone groups and antimicrobial metal ions that are ionically bonded with these sulfone groups." JP `855 does not disclose or suggest any transparent device, let alone a contact lens or a method of making a contact lens.

Examiner has stated that "it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation the soft contact lenses produced would have antimicrobial properties." Page 5, July 19, 2007 Office Action.

Claim 55 recites a method for producing an antimicrobial lens comprising a monomer of Formula I. Claim 63 recites "a method for reducing the adverse events associated with microbial production in the eye of a mammal comprising providing an antimicrobial lens" comprising a monomer from formula I



wherein R^1 is hydrogen or C_{1-6}alkyl; and R^2 is selected from (in relevant part) $-OR^3$, or $-(CH_2)_d-R^3$.

Neither acetylacetonate nor benzoylacetonate disclosed in JP `181 has an acryl group in the position required in claims 55 and 63, nor is there any suggestion in JP `181 that an acryl group should be included. Neither acetylacetonate nor benzyolacetonates are recited in claim 1. Further the definitions of the substituents for R^3 do not include ketones, such as 2-propanone or 3-benzyl-2-propanone. (See claim 1, lines 14-23).

There is absolutely no suggestion in JP `181 that other monomers, let alone the monomers of Formula I should be used. In fact, as discussed above, JP `181 suggests that if an antimicrobial other than the disclosed acetylacetonate or benzyolacetonates are used, it be a non-metal containing antimicrobial. Examiner has sought to cure fill this deficiency by relying on seven additional references, Vanderlaan et al, Laskey, Bennett, Young, Malecki, Tilley and JP `855, which are described individually above. Vanderlaan et al, Laskey, Bennett and Young are absolutely silent as to antimicrobial contact lenses of any kind, let alone those comprising silver and the monomer of Formula I. Malecki et al. and Tilley also do not disclose or suggest contact lenses, do not disclose or suggest monomers of Formula I for any purpose, let alone contact lenses comprising silver and formed from the monomers of Formula I. JP `855 does not disclose or suggest any ophthalmic device, and does not disclose or suggest the polymers disclosed therein would have any properties useful for an ophthalmic device, such as transparency, or on eye lens movement.

The Examiner has the initial burden of providing some substantial line of reasoning supporting the combination of references. This has not been done in this case.

The Examiner acknowledges this stating "the difference between the prior art and the claimed invention is that the prior art does not expressly disclose an antimicrobial contact lens comprising silver and a polymer comprising a monomer of formula I." Page 4-5, July 19 office action. Examiner goes on to state

"it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation the soft contact lenses produced would have antimicrobial properties and be time releasable will

having long-term effectiveness and, thus, avoid the problems associated with extended wear."

However, Examiner points to no basis for this conclusion and there is no substantial line of reasoning describing how one of skill in the art, armed only with references which do not suggest methods for making or using antimicrobial contact lenses comprising silver and formed from polymers comprising monomers of Formula I.

Instead, it is clear, that the Examiner has taken the claims of the present invention and used it as a template to "pick and choose" among elements from nine different references.

Examiner has provided no convincing reason why one of skill in the art would replace the antimicrobial components disclosed in JP `181 with certain ligands disclosed in JP `855, instead of those disclosed in Tilley or Malecki (which not included within Formula as recited) or with other antimicrobial components such as the zeolites disclosed in EP `314, or the other antimicrobial components specifically disclosed in JP `181.

Assuming aruendo, that a prima facie case of obviousness has been made (which Applicants disagree), Applicants submit that the present Examples include a showing of surprising results sufficient to rebut said presumption.

The presently recited lenses provide both antimicrobial activity and on eye movement. Applicants were surprised to find that certain silver containing lenses did display adequate movement on a statistically significant number of patients. Figures 1 and 2 clearly show that the percentage of lenses displaying movement on eye decreases as the concentration of antimicrobial metal increases above about 200 ppm. There is no suggestion in any of the references that antimicrobial metal concentration would have any impact on on-eye movement. In fact, not one of the references which discloses a contact lens formulation discloses any on eye testing.

The only reference which discloses a concentration range for silver ions in a polymer is JP `855, which discloses ranges of 0.0009 – 0.9 mmol/gm and 0.0045 –0.45 mmol/gm. The upper limit of 200 ppm recited in amended claims 55 and 63 converts to 0.00185 mmol/gm which is at the very lower limited of the broadest disclosed range, and less than half the lower limit of the preferred range. The upper limits disclosed in JP `855 are about 400 and about 200 times greater than the presently recited 200 ppm. Clearly

the combination of JP `181, JP `855 and the other references neither recognize the problem faced by Applicant or suggest the solution recited in the present claims.

Applicants respectfully submit that the rejections of claims 55-61 and 63 in view of JP 05-269181 in view of Vanderlaan et al., Laskey, JP 55-38855, Malecki et al., Tilley, Bennet and Young has been traversed.

Claims 63-72 have also been rejected as unpatentable over JP 05-269181 in view of Vanderlaan et al., Laskey, JP 55-38855, Malecki et al., Tilley, Bennet and Young. Claims 68-71 have been amended to recite that the contact lenses comprising up to about 200 ppm silver. For the reasons discussed above, Applicants respectfully submit that claims 68-71 are patentable over the cited references. Claims 64-67 and 72 recite lenses displaying on eye movement on a recited percentage of a patient population. As discussed above, none of the references cited by Examiner disclose or suggest this result. In fact, the references which disclose contact lenses are absolutely silent as to factors which impact on eye movement on any lens, let alone an antimicrobial contact lens and disclose no clinical data at all. It would thus appear that none of the prior art cited even put contact lenses on a patient's eye, let alone evaluated on eye movement. Accordingly, Applicants respectfully submit that claims 64-67 and 72 are patentable over the art of record as they recite a combination of properties (antimicrobial lenses having on eye movement), which was neither evaluated, considered or disclosed by the prior art of record. Figures 1 and 2 clearly show that lenses without an antimicrobial agent, and lenses with antimicrobial agents in certain concentrations display acceptable on-eye movement in substantial percentages of patient populations, while lenses outside the concentration ranges disclosed do not. Applicants respectfully submit that the rejections of claims 64-67 and 72 in view of JP 05-269181 in view of Vanderlaan et al., Laskey, JP 55-38855, Malecki et al., Tilley, Bennet and Young has been traversed.

Examiner has further rejected claims 55-61, 63 -72 in view of EP 1050314 in view of Vanderlaan et al., Laskey, JP 55-38855, Malecki et al., Tilley, Bennet and Young.

EP `314 discloses contact lenses which contain ceramic carriers, such as zeolites which retain antimicrobial metal ions. The zeolites may be coated onto a preformed

contact lens or incorporated into the lens precursor prior to polymerization. EP `314 neither discloses nor suggests that reactive monomers, such as those of Formula I could be used instead of the zeolites disclosed by EP `314. EP `314 is also silent as to lens movement.

Vanderlaan et al., Laskey, JP 55-38855, Malecki et al., Tilley, Bennet and Young have been discussed above, and as discussed above, do not cure the deficiency of EP `314. Accordingly, Applicants submit that the rejection of claims 55-61, 63 -72 based upon the combination of EP 1050314 in view of Vanderlaan et al., Laskey, JP 55-38855, Malecki et al., Tilley, Bennet and Young have been traversed for the reasons detailed above with respect to the rejection based upon JP `181 and the seven secondary references.

Examiner has further rejected claims 55-61 and 63-72 as unpatentable over the nine references discussed above in further combination with either US 5,011,275 ("Meuller et al.") or US 4,038,264 ("Rostoker et al.")

Mueller et al discloses polymers which "are machinable in the dry state and form clear hydrogels". Abstract. Meuller discloses that a component of the polymer may be, among other monomers, "an ethylenically unsaturated sulfonic acid". Col. 4, lines 39-40. Rostoker et al. discloses hydrophilic copolymers "having unusually high oxygen permeability compared to other hydrophilic polymers." Abstract. Rostoker et al. discloses that 2-acrylamide-2-methylpropane sulfonic acid may be included as a comonomer. However, both Mueller et al. and Rostoker et al. are silent as to the inclusion of any antimicrobial component, an antimicrobial metal, or disclosure relating to the movement of the lenses on eye. Neither patent includes any clinical data or suggests that contact lenses were evaluated on eye.

The rejection does not provide any which might form a basis for a prima facie case of obviousness. The Examiner does not even state how the 11 cited documents are to be combined to support the conclusions made by the Examiner. The Examiner states "[t]he prior art discloses the complexes of silver with ligands and contact lenses containing the same" and "the prior art amply suggests the same as antimicrobial soft contact lenses comprising silver and a polymer comprising a monomer of formula I." Page 6, July 19, 2007 Office Action.

"Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some rational underpinning to support the legal conclusion of obviousness." In re Kahn, 441, F.3d. 977, 988 Fed. Cir. 2006.

This rational underpinning is completely absent with respect to the rejections based upon the combination of JP 05-269181 or EP1050314, each in view of Vanderlaan et al. (US 5,998,498), Laskey (US 3,929,741) JP 55-38855, Malecki et al. Tilley, Bennet and Young in further combination with either US 5,011,275 ("Mueller et al.") or US 4,038,264 ("Rostoker et al.")

However, assuming Examiner could make a prima facie showing of obviousness based upon some combination of the 11 cited references, Applicants have, as discussed above, clearly shown surprising results in the form of on-eye movement sufficient to rebut such a showing. Mueller et al. and Rostoker et al., like the other nine cited references, disclose no clinical results, and are silent as to both antimicrobial activity and on-eye movement.

Claim 62 has been canceled. Accordingly the rejections of that claim over JP `885 in view of Ulmer et al.is now moot.

Examiner has further rejected claims 1, 4-11, 14-17, 19, 21-24, 55-61, 68-70, 73-75 on double patenting grounds over copending Applications 10/703,770 or 10/734,762. Applicants respectfully disagree. The claims of copending application 10/703,770 are patentably distinct from the claims of the present invention and recite the additional element

(a) curing a reactive monomer mix comprising at least one lens forming component and at least one ligand monomer under conditions sufficient to provide a reactivity ratio of the ligand monomer to at least one major lens forming component of at least about 0.45 lens; and

(b) treating said lens with a silver solution to form an antimicrobial lens comprising silver in an amount which is at least about 80% of target silver concentration,

Copending application 10/734,762 has been abandoned.

Applicant respectfully submit that the Examiners rejections have been traversed and that the claims as amended are patentable over the cited references. Withdrawal of the rejections and allowance of the claims as amended is respectfully submitted. If the Examiner is of a contrary view, the Examiner is requested to contact the undersigned attorney at (904) 443-3074.

Respectfully submitted,

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